

### REMARKS

The Examiner rejected claims 1-31. Claims 1-31 have been canceled herein, and claims 48-77 have been added. Thus, claims 48-77 are pending. Claims 48-57 recite dietary supplements containing a grape seed extract in combination with a grape skin extract and at least one enzyme, where the grape seed extract is 3.3 percent or more of the supplement. Claims 58-67 recite dietary supplements containing a grape seed extract in combination with a grape skin extract and at least one enzyme, where the grape seed extract and the grape skin extract combined is 32 percent or more of the supplement. Claims 68-77 recite a method for providing a mammal with a dietary supplement containing a grape seed extract in combination with a grape skin extract and at least one enzyme. Claims 68-77 also recites that either (a) the grape seed extract is 3.3 percent or more of the supplement, or (b) the grape seed extract and the grape skin extract combined is 32 percent or more of the supplement.

Support for these new claims can be found throughout Applicant's specification. For example, Applicant's specification provides multiple working examples of dietary supplements containing (a) a grape seed extract, a grape skin extract, and an enzyme, where the grape seed extract is 3.3 percent or more by weight of the supplement, and (b) a grape seed extract, a grape skin extract, and an enzyme, where the grape seed extract and the grape skin extract combined is 32 percent or more by weight of the supplement. See, e.g., page 17, lines 16-35, and page 20, line 31 through page 21, line 8. Thus, no new matter has been added. In light of these amendments and the following remarks, Applicant respectfully requests reconsideration and allowance of claims 48-77.

#### Rejections under 35 U.S.C. § 112, first paragraph

The Examiner maintained the rejection of claims 1-31 under 35 U.S.C. § 112, first paragraph, as containing subject matter not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the Examiner stated that the specification does not support the breadth of claims 1-14 and 22-31, and that the specification does not contain evidence that any plant extract mixed with a digestive enzyme would perform as effectively as PROVEXCV™. The Examiner also stated that the instant specification does not provide a

working example that indicates that mixtures of individual components of PROVEXCV™ would display similar effects *in vivo*, and that rigorous testing would be required and would constitute an undue burden of trial and error experimentation.

In addition, the Examiner stated that the specification lacks guidance that would allow an ordinary artisan to make the composition of the invention. Specifically, the Examiner stated that the specification does not contain information about the plant extraction procedures, and that the ordinary artisan is left to choose which type of extract to purchase or which extraction protocol to use. Further, the Examiner stated that it would require undue experimentation to create a composition that would display results parallel to those provided in the specification regarding PROVEXCV™.

Applicant respectfully disagrees. To further prosecution, however, claims 1-31 have been cancelled herein without prejudice. Thus, this rejection is moot.

Applicant's specification fully enables claims 48-77. In fact, a person having ordinary skill in the art reading Applicant's specification would have been able to make and use the presently claimed invention without undue experimentation. For example, a person having ordinary skill in the art would have been able to follow Applicant's specification to make the recited supplements by combining a grape seed extract with a grape skin extract and at least one enzyme such that either (a) the grape seed extract is 3.3 percent or more of the supplement, or (b) the grape seed extract and the grape skin extract combined is 32 percent or more of the supplement. No undue experimentation is needed to make and use such supplements.

In light of the above, Applicant respectfully requests withdrawal of the rejections under 35 U.S.C. § 112, first paragraph.

#### Rejections under 35 U.S.C. § 102(b)

The Examiner maintained the rejection of claims 1-5, 9-11, and 22 under 35 U.S.C. § 102(b) as being anticipated by Balch *et al.* for the reasons set forth in previous Office Actions dated October 27, 2000 and June 22, 2001. In the previous Office Actions, the Examiner stated that the Balch *et al.* reference refers to compositions containing flavanoids and digestive enzymes, which "were known at the time of the Instant application."

Applicant respectfully disagrees. To further prosecution, however, claims 1-5, 9-11, and 22 have been cancelled without prejudice. Thus, this rejection is moot.

Present claims 48-77 are not anticipated by the Balch *et al.* reference. At no point does the Balch *et al.* reference disclose a supplement combining a grape seed extract with a grape skin extract and at least one enzyme such that either (a) the grape seed extract is 3.3 percent or more of the supplement, or (b) the grape seed extract and the grape skin extract combined is 32 percent or more of the supplement.

In light of the above, Applicant respectfully requests withdrawal of the rejections under 35 U.S.C. § 102(b).

#### Rejections under 35 U.S.C. § 103(a)

The Examiner maintained the rejection of claims 1-24 under 35 U.S.C. § 103(a) as being unpatentable over Gaynor *et al.* (U.S. Pat. No. 5,904,924) in view of Balch *et al.* and further in view of Handel *et al.* (U.S. Pat. No. 5,387,422), for reasons set forth in Office Actions dated October 27, 2000 and June 22, 2001. In the previous Office Actions, the Examiner stated that (1) Gaynor *et al.* "created a composition comprising grape seed extract, grape skin extract, bilberry, and ginkgo biloba extract," (2) Balch *et al.* teach that digestive enzymes such as bromelain aid in digestion, and (3) Handel *et al.* taught "that fungal proteases obtained by *Aspergillus* were also acid stable." The Examiner also stated that one of ordinary skill in the art "would have been motivated to combine the composition disclosed by Gaynor *et al.* with a protease composition comprising a fungal protease, an acid stable protease and bromelain in order to effectively aid digestion of the composition."

Applicant respectfully disagrees. To further prosecution, however, claims 1-24 have been cancelled without prejudice. Thus, this rejection is moot.

The Balch *et al.* reference discloses that quercetin may effectively treat and prevent asthma and should be taken in conjunction with bromelain to enhance absorption. The Handel *et al.* reference discloses using a proteolytic enzyme food supplement containing an acid protease fungal enzyme and a semi-alkaline protease fungal enzyme to convert ingested dietary protein into free amino acids and short chain peptides. The Gaynor *et al.* reference discloses a 969 gram mixture of 55 dried ingredients ranging from bee pollen and dandelion to biotin and inositol.

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The total weight of the listed ingredients in columns 4-5 is 27,826.75 mg. According to the Gaynor *et al.* reference, 40 mg of this mixture is disclosed as being grape seed extract, which represents less than 0.15 percent of the listed ingredients. In addition, 300 mg of this mixture is disclosed as being grape skin, which represents less than 1.1 percent of the listed ingredients. The amounts of grape seed extract and grape skin disclosed in the Gaynor *et al.* reference are far less than the amounts of grape seed extract and grape skin extract recited in the present claims. Moreover, at no point do the cited references, either alone or in combination, teach or suggest a supplement combining a grape seed extract with a grape skin extract and at least one enzyme such that either (a) the grape seed extract is 3.3 percent or more of the supplement, or (b) the grape seed extract and the grape skin extract combined is 32 percent or more of the supplement. Thus, present claim 48-77 are not obvious.

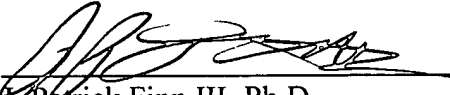
In light of the above, Applicant respectfully requests withdrawal of the rejections under 35 U.S.C. § 103(a).

#### CONCLUSION

Applicant respectfully submits that claims 48-77 are in condition for allowance, which action is requested. Enclosed is a check for excess claim fees and the Petition for Extension of Time fee. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: July 11, 2002

  
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In the claims:

Claims 1-31 have been cancelled.

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